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10/587,722	07/27/2006	Andrew Ian Cooper	T3110(C)	2308
201	7590	10/07/2010	EXAMINER	
UNILEVER PATENT GROUP 800 SYLVAN AVENUE AG West S. Wing ENGLEWOOD CLIFFS, NJ 07632-3100				ALAWADI, SARAH
ART UNIT		PAPER NUMBER		
		1619		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

[patentgroupus@unilever.com](mailto:patentgroupus@unilever.com)

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/587,722	COOPER ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	SARAH AL-AWADI	1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 19 March 2010.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-4 and 6-23 is/are pending in the application.
- 4a) Of the above claim(s) 8-20 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-4,6 and 7 and 21-23 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## **DETAILED ACTION**

Receipt of the RCE filed on 02/17/2010 has been acknowledged. The Examiner acknowledges the following:

Claims 1, 4, 6-7, and 22 are amended.

Claim 23 is newly added.

## **MAINTAINED REJECTIONS**

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1-3, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Barby et al. United States Patent 4,522,953 as evidenced by A. Charlesby, *Solubility and Molecular Size Distribution of Crosslinked Polystyrene*.**

Claim 1 recites a composition of porous bodies which are soluble in non-aqueous media comprising a three dimensional water in oil open-cell lattice containing 10-95% by weight of a polymeric material which is soluble in hydrophobic or water immiscible non-aqueous media and 5 to 90% by weight of a surfactant which is soluble in non aqueous media, said porous bodies having an intrusion volume as measured by mercury porosimetry of at least 3ml/g; and wherein a water soluble material and/or a water-insoluble material, neither of which is soluble in the non-

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aqueous media is incorporated into the lattice of said porous bodies to be dispersed in the non-aqueous media when said porous bodies dissolves in the non-aqueous media in less than 3 minutes.

Reference '953 discloses porous bodies such as porous polymeric materials (abstract). The polymer material of the invention can consist of at least 90% by weight (column 2, lines 60-63) and the polymer material can be made of lightly cross-linked polystyrene. As evidenced by Charlesby, lightly cross-linked polystyrenes have the ability to dissolve in non-aqueous media. (see fig2. and conclusion page 7). The porous bodies can contain an aqueous or non-aqueous liquid. (claim 3) The liquid can be hydrophobic (claim1) and the porous polymeric block material is formed from a water in-oil emulsion. The optimum concentration of surfactant by monomers is 20%. (column 5, lines 65-67) The surfactant (emulsifier of '953) is soluble in the non-aqueous media as Example 1 discloses mixing the surfactant with divinylbenzene. (see also column 6, lines 1-15) The structure can be a three dimensional open-cell lattice because reference '953 teaches that porous polymer beads can be compressed and bonded together, and that the interior of the blocks is homogenous and that blocks are uniform in pore and cavity distribution. (column 3 and 4, lines 67 and line 1-5) Furthermore regarding claims 1 and 2, the porous blocks can be in any desired shape, and does not restrict the process to containers in which agglomeration of beads under pressure can be carried out, thus can include the process of forming beads. (column 6, lines 31-35) Reference '953 teaches that the porous polymeric material can have a dry density of between 0.02 to 0.08g/cc (or ml/g) comprising linked pores having a pore volume of more than 9cc/g ( 9ml/g) and contained in an aqueous or non-aqueous

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media. (column 2, lines 54-59) This anticipates the claimed intrusion volume range of at least 3 ml/g.

Claim 3 recites that the porous bodies as claimed in claim 1 are made of polymeric material wherein the homopolymer or copolymer is made from monomer such as styrenics. Reference '953 teaches that the polymer material can be made of lightly cross-linked polystyrene. (column 5, lines 3-5) This is a type of styrenic as defined by the instant specification page 2, line 2. Furthermore, absent evidence to the contrary, as it is only lightly cross-linked, it is expected that at least a small amount will dissolve in non-aqueous media.

Claim 22 recites a product by process limitation step for the composition which holds little patentable weight, see MPEP 2113. Although Reference '953 teaches a different process to produce the porous body, Applicants process could be used to produce a porous body with the same characteristics as Reference '953. Applicant's porous body described in product by process terms, reasonably appears to encompass porous bodies that are indistinguishable from the porous bodies of Reference' 953 produced by a different process.

Regarding claim 23, MPEP 2112.01 (II) recites that "products of identical chemical composition can not have mutually exclusive properties. A chemical composition and it's properties are inseparable."

**Claims 1-3, 6-7, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated**

**by Kitagawa, Naotaka PCT/ US98/12797 as cited on IDS form filed 08/23/2006.**

Regarding claims 1-2, Reference '797 teaches the production of porous crosslinked hydrophilic polymeric microbeads wherein at least 10% are spherical and the polymeric material is 30 % by weight of the emulsion. (page 4, line 19, and line 28, and page 14, line 14) The invention consists of 50% of the total polymerizable monomer that are hydrophilic. (page 5 line 30) Furthermore, a single monomer or mixture of types can be used in the emulsion such as hydrophilic and hydrophobic monomers. Nonionic surfactants may be present as a type of emulsifier in an amount of 1 to about 30 wt. percent. (page 16 lines 15-17 and page 17, lines 1-4) The emulsions may be either water-in oil or oil-in-water type emulsions. (see Example 2, page 35 lines 1-10 and Table 2) The fact that the porous bodies have a mercury porosimetry of at least 3 ml/g is an intended property of the composition. Example 30 of reference '797 teaches the use of an alcohol (non-aqueous) containing emulsion.

Regarding instant claims 3 and 4, reference '797 teaches an example of porous bodies that contain polystyrene/divinylbenzene which is a type of styrenic.

Claim 6-7 recites that the porous bodies have water soluble and water insoluble materials including polymers incorporated within. Reference '797 teaches that a single monomer or mixture of types can be used in the emulsion such as hydrophilic and hydrophobic monomers. (page 14, lines 3-12) The composition can include suitable stabilizers such as polyethylene glycol which is a soluble material. (page 17, lines 24-31) The hydrophilic porous bodies can be used as carriers to provide sustained release of an agent such as fragrance, insecticides or a cosmetic. (page 28, lines 31-34)

Claim 22 recites a product by process limitation step for the composition which holds little patentable weight, see MPEP 2113. Although Reference '797 teaches a different process to produce the porous body, Applicants process could be used to produce a porous body with the same characteristics as Reference '797. Applicant's porous body described in product by process terms, reasonably appears to encompass porous bodies that are indistinguishable from the porous bodies of Reference '797 produced by a different process.

Regarding claims 21, and 23, MPEP 2112.01 (II) recites that “products of identical chemical composition can not have mutually exclusive properties. A chemical composition and it’s properties are inseparable.”

## **RESPONSE TO REMARKS**

Regarding the rejections over and Barby and Kitagawa, Applicants argue that their invention forms an emulsion of water in a water immiscible liquid which contains a preformed polymer which is soluble in the water immiscible liquid. Applicants argue that the porous materials disclosed by Barby and Kitagawa are cross-linked polymers and are incapable of dissolving or dispersing when contacted with non aqueous media in less than three minutes and are not comprised of a three dimensional open cell lattice comprised of a polymeric material which is soluble in water immiscible non-aqueous media.

In response, the Examiner respectfully submits that the claim recites the porous body dissolves. It does not recite that it has to completely dissolve or under what conditions. If the body is even somewhat soluble or dispersible in any solvent, some will dissolve or disperse. Absent evidence to the contrary, if the porous bodies of the art were placed in the proper medium

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and heated or agitated, it is an expected property that a portion will dissolve. Furthermore, the Polymer Science Textbook submitted by Applicants teaches that solubility varies depending on the degree of cross-linking and nature of the solvent or temperature, and that the absence of solubility does not imply crosslinking. The polymers of Barby and Kitagawa are likely to at least partially dissolve in non aqueous media as demonstrated by Charlseby. Furthermore, the rate of the dissolving is a property of the composition as it is expected that even just a fraction of the bodies will dissolve in less than thirty seconds with appropriate mixing as the claim does not specify that it has to completely dissolve. Thus, absent evidence to the contrary it is expected that a small portion of the porous bodies dissolve under appropriate conditions and that even a portion would necessarily dissolve in less than thirty seconds as a mixture is occurring.

Regarding claim 22, the claim states that the porous bodies as claimed in claim 1 wherein said porous body are made by a process comprising the steps of providing an intimate mixture of polymeric material and surfactant in liquid, providing a fluid freezing medium at a temperature effective for rapidly freezing the liquid medium, cooling the liquid medium with the fluid freezing medium at a temperature below the freezing point of the liquid medium for a period effective to freeze the liquid medium, freeze drying the frozen liquid medium to form the porous bodies by removal of the liquid medium by sublimation. Although Barby and Kitagawa uses different process to produce the porous body, Applicant's process could be used to produce a porous body with the same characteristics as the reference's porous body. Therefore, applicant's porous body, described in product-by process terms, reasonably appears to encompass porous bodies that are indistinguishable from the reference porous bodies produced by a different process. Since the patent office does not have facilities to perform comparisons between claimed

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materials and prior art materials, a lesser burden of proof is required to make a *prima facie* case of obviousness for products claimed in terms of the process used to make them. Therefore, the invention as claimed is seen as *prima facie* obvious. (see MPEP 2113)

\*It is recommended that Applicants amend a solvent or specific solvent types into claim 1 in order to further distinguish from Barby and Kitagawa.

## NEW REJECTIONS

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6-7, and 21-23 rejected under 35 U.S.C. 103(a) as being unpatentable over Bausch et al. United States Patent Application 2004/0096515, as evidenced by Mork et al. 6,147,131.

Bausch et al. teach porous beads that have shells formed of biocompatible spherical particles linked by van der Waals forces, see paragraph 0009. The porous beads are three dimensional as shown in figures 3-11. The shell has a plurality of pores extending there through, thus is porous, see paragraph 0009. Particles used to form the oil-and-water interface include that of polymers such as polystyrene, see paragraph 0038. The polystyrene shell is formed in organic solvents of which it is soluble in such as toluene, see paragraph 0049. The active agents can be selected so that they dissolve in a compatible solvent and are incorporated into the water in oil emulsion, se paragraph 0057. Surfactants are used including that of Triton, see paragraph 0052. The active agents can include that of pharmaceutical active agents, drugs, fragrances, or vitamins, see paragraph 0058. The particles of Bausch can be made of particles (i.e. polystyrene) which are easily dissolved and release the active agents, see paragraph 0059. The fact that the materials (i.e. vitamins) are dispersed in non-aqueous media when the porous bodies dissolve in the non-aqueous media is an expected property that occurs when the polymeric shell dissolves in the non-aqueous solvent, as the porous bodies are not miscible with the non-aqueous solvent. Regarding the porosimetry and the time period it takes the porous body to dissolve in non-

aqueous media after stirring, MPEP 2112.01 (II) recites that “products of identical chemical composition can not have mutually exclusive properties. A chemical composition and it’s properties are inseparable.” As the porous bodies are composed of the same components of Applicant’s claims, it is expected that the porous bodies would demonstrate the same properties.

Claim 22 recites a product by process limitation step for the composition which holds no patentable weight, see MPEP 2113. Applicant's porous body described in product by process terms, reasonably appears to encompass porous bodies that are indistinguishable from the porous bodies of Bausch et al. produced by a different process.

Bausch et al. does not teach the amount of surfactant to be added, however, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to optimize the amount of surfactant for the water-in-oil emulsion in order to properly stabilize the emulsion. It is known in the art as evidenced by Mork et al. (US 6,147,131, column 1, lines 44-50) that surfactants must be used in concentrations above 5% to effectively stabilize an open celled structure. Furthermore it would have been obvious to adjust the amount of the surfactant because MPEP 2144.04 recites “where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine optimization.”

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1-4, 6-7, and 21-23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

applicant regards as the invention. Claim 1 recites a “water soluble material and/or a water-insoluble material, neither of which is soluble in the non-aqueous media.” This is particularly confusing as if the water-insoluble material is not soluble in aqueous media (i.e. water insoluble), and is also not soluble in non-aqueous media, what media is the water-insoluble material soluble in? It is also confusing if Applicants intend for the materials to be insoluble in only the non-aqueous material used for forming the porous bodies, or if it is intended to be insoluble in all non-aqueous media. Please clarify.

*Correspondence*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarah Al-Awadi whose telephone number is (571) 270-7678. The examiner can normally be reached on 9:30 am - 6:00 pm; M-F (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bonnie Eyler can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated

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information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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